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Denfotex Ltd.
Wyndham
Hophurst Hill
Crawley Down
West Sussex, RH10 4LP

Patents ADP number *(if you know it)*

767333 6001

If the applicant is a corporate body, give the country/state of its incorporation

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See A/C 1.22

4. Title of the invention

"Method and apparatus for filling a dental root canal"

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Brookes & Martin

High Holborn House
52/54 High Holborn
London WC1V 6SE

Patents ADP number *(if you know it)*

471001

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Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

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11. I/We request the grant of a patent on the basis of this application.

Signature Brookes & Martin Date 14 January 2000

BROOKES & MARTIN

12. Name and daytime telephone number of person to contact in the United Kingdom: 0171 242 9631 - David C. Woodcraft

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METHOD AND APPARATUS FOR FILLING A DENTAL ROOT CANAL

This invention relates to the treatment of a dental root canal including the obturation of the canal.

Background of the Invention

There are a number of situations in which treatment of root canals in teeth is indicated. The tissue lying within the tooth structure, the dental pulp, may become diseased as a result of dental caries or the cells and tissue may be traumatised or atrophy. As a result of this, the pulp tissue may die and/or become infected. This leads to death of the pulp. The treatment of choice is the removal of the diseased tissue and achieving a cell and bacteria free root canal using mechanical methods of tissue removal. These operations are technically difficult and require the accessing of the canal and removing infected tissue, which may be at or near the apex of the root of the tooth. The treatment becomes more complex as the anatomy of the root canal becomes more complex and the canals themselves become narrower.

Conventional treatment involves gaining access to the pulp chamber by removing the overlying enamel and dentine. Once the pulp chamber is exposed, the entrances to the root canals are then located and enlarged. The length of the root canal is calculated from a diagnostic radiograph or by means of an apex locator and the canal is instrumented using files and/or reamers of increasing size. These instruments are designed to remove the internal surface of the root canal by rasping and cutting the dentine walls. The dentine walls have small holes where the dentine forming cell processes track into the dentine. These holes are sites where bacteria can settle and proliferate. It is these areas which are reduced by mechanical

debriding of the internal surface of the root canal. To achieve this, the reamers and files are used to produce a root canal that, near the apex, is matched in size to the obturating device. The internal diameter of the canal is enlarged so that the cavities in the root wall are reduced in size and the canal is mechanically cleaned.

Medicaments may be used to chemically kill the bacteria; these are usually disinfectants and anti-bacterials such as hypochlorite solution or antibiotic pastes. These may be introduced into the root canal after initial mechanical debridement. These medicaments and mechanical methods of removal of tissue are designed to produce a root canal which is free of bacteria and other contaminants. Conventional procedures are time consuming and difficult to carry out since they require use of copious volumes of irrigants such as aqueous sodium hypochlorite to flush out the canal. The more posterior the tooth situation within the mouth the greater the risk of failure to achieve the objectives, since the root canals morphology becomes more convoluted and adequate access becomes more difficult to achieve.

Summary of the Invention

An important objective of the present invention is to simplify the treatment of dental root canals and to provide a treatment system which enables the dentist to be more confident that remnants of decay and bacterial contamination within the canal have been removed, prior to obturation of the canal.

Another object is to reduce the time normally required to prepare a root canal for obturation and also preparing the canal for alternative systems of obturating the canal which can be co-ordinated with the preparation of the canal.

According to one aspect of the invention there is provided a method of treating dental root canal which comprises the steps of:-

(a) gaining access to the root canal;

(b) introducing a flowable photosensitiser into the root canal;

(c) activating the photosensitiser by exposing the walls of the root canal to laser light via an optical fibre within the root canal to kill bacteria within the root canal; and

(d) obturating the root canal.

As mentioned above, the root canal is first opened up and necrotic material removed by filing or reaming. One convenient method of cleaning out the root canal is by using endodontic instruments having a tapered profile. Normally, a series of instruments are used of increasing length and decreasing diameter in order to form a conical shaped canal which tapers downwardly to the apex. These instruments may be used both manually or, conveniently, may be fitted to a conventional rotary dental handpiece. During and after the canal shaping step, debris loosened by the mechanical debriding of the interior and walls of the canal is removed by irrigation and organic debris dissolved. Traditionally, aqueous sodium hypochlorite solution is used, e.g. at a concentration of 2~3%. These are used in copious volumes during the debriding procedure to remove solid debris or kill bacteria (Chow et al, 1983, J. Endodont. 9,475).

In the method of the present invention, sodium hypochlorite may be used for initially cleaning and flushing away loosened debris. However, an aqueous solution of

the photosensitiser may alternatively be used in this step, or at least after the initial debris has been removed and the hypochlorite solution flushed away.

The next step is to introduce the photosensitiser dye into the root canal. Preferably, the photosensitiser is a toluidine blue dye which is employed in an aqueous solution, although other photosensitisers may be used as mentioned in EP 0637976. On contact with the bacteria, the dye or other photosensitiser conjugates with the bacteria and once photosensititation has occurred, the site is irradiated with light of a specific wavelength which is strongly absorbed by the photosensitiser. The wavelength of light is specific to the absorption of each photosensitiser. The activation of the dye leads to singlet oxygen release and results in death of the bacteria. It is important that the light is guided closely to areas which may be contaminated with bacteria. This is best done by introducing a light guide or optical fibre into the root canal. In order to ensure that the light is directed onto the walls of the root canal, the fibre tip should be appropriately shaped. The optic fibre may have a spherical or cylindrical surface in the region of the distal end. The production of this type of tip or emitter is described in US Patent No. 5,073,402. In essence, the tip is preferably formed by contacting the distal end of the optic fibre with a light-curable composition, which in its cured state is transparent or translucent, while passing coherent light through the fibre at a wavelength causing curing of the composition. Suitable light-curable compositions include acrylate and methacrylate monomers, including epoxy and urethane acrylates and methacrylates. Such compositions may contain photochemical initiators and free radical generating additives such as α-diketones (camphoroquinone), benzoyl peroxides and dimethyl-p-toluidine. A

generally isotropic tip can be formed by immersing the optic fibre tip in a bath of a light-curable composition, e.g. as described in US Patent No. 5,073,402. The shape of the tip may be predetermined, e.g. a cylindrical tip may be formed by introducing the fibre tip into a tube containing the polymerisable composition. By selecting a polytetrafluoroethylene (PTFE) or silicone tube, it can be readily stripped away after the light-curable resin has been polymerised.

After the root canal has been treated with the photosensitiser and irradiated with light, the root canal is dried, e.g. by aspiration and using absorbent points. The canal is then obturated using a suitable system to seal the canal. This may involve the use of conventional sealing system such as shaped gutta percha, silver or titanium points cemented with an endodontic sealer. Examples of these include zinc oxide/ eugenol and calcium hydroxide based cements and also epoxy resins. Conventional obturation systems may be used such as those employing gutta percha are generally convenient. One suitable system involves introducing gutta percha in heated, softened form on a rod-like carrier into the canal. This procedure is described in European Patent Application No. 0337024. A similar procedure is described in US Patent No. 5149268.

Alternatively, the canal is obturated with a light-curable filling composition. The light curable composition may be cured by irradiation by light of a wavelength specific to activate the in situ system, introduced through an optical fibre positioned within the root canal. The optical fibre is generally provided with a distal tip for spreading the light substantially uniformly, and may be the same optical fibre that is used to guide light into the canal to activate the photosensitiser. However, it may be

necessary to use light of a different wavelength for curing the sealant than for activating the photosensitiser. After the filling material has been cured, the optical fibre may remain entombed in the root canal as part of the obturation.

The invention also includes a kit of parts for treating a dental root canal which comprises:-

(a) a flowable photosensitiser;

(b) an optical fibre having a distal portion for emitting light and adapted for introduction into a root canal so that the tip is capable of reaching the apical region of the root canal, said optical fibre being connectable proximally with a means for generating light; and

(c) obturating means for sealing the canal.

In one form of the invention, the obturating means is a flowable, light curable filling composition.

It will be appreciated therefore that in one aspect the invention makes use of a combination of a photosensitive substance and a light source operating at the appropriate wavelength to activate the photosensitiser. A further aspect of the invention is the delivery mechanism, which permits the delivery of the photosensitiser either at or near the apex of the root canal to ensure that the photosensitiser will contact the debris and bacteria. A related aspect of the invention is the provision of a specially shaped spherical or cylindrical tip to an optical fibre which permits application of light of appropriate wavelength to the region of the apex of a tooth. A still further aspect is the provision of a specially shaped optical tip to provide uniform light near the apex of the tooth. A further element is the provision of a novel sealing

or filling material, which will prevent re-infection of the canal from either the access cavity or via the apical foramen. The sealing or filling material may be delivered via the novel delivery system.

As mentioned above, the pulp chamber and coronal region of the root canal is accessed in the normal way using a high speed dental drill. Alternatively, a laser may be used to expose the pulpal chamber and the entrance to the root canal. After initial estimation of canal length which may be carried out by radiography or use of electro optical detection devices, the canal opening may be increased by reaming the canal. The canal may then be irrigated with a known irrigant such as with aqueous hypochlorite or more preferably with the photosensitiser. This may be achieved using a fine tipped syringe or, alternatively, with a specialised dispensing accessory as described below. Turbulent flow may be induced when injecting the photosensitiser into the canal as described in Gooden, 1976, 2: 2571, Chow J. Endodont 1983 9.47. Effective irrigation is achieved by preparing an inwardly tapered canal to ensure the irrigants reach to the apex. This may be facilitated by the use of appropriate instruments.

After introducing the photosensitising agent into the root canal in the tooth, the agent is activated using light delivered by an optical fibre from the specific light source. The wavelength employed depends on the absorption spectra of the photosensitiser. Toluidine blue O is preferably employed as the photosensitiser and has an absorption maximum in the range of 630~660 nm. Semiconductor lasers, gallium/arsenide and helium/neon lasers may be used. The laser light may be continuous or pulsed. It has been found to be important to spread the laser light

within the canal rather than focus it on a small target area. One way of achieving this is to provide an optical fibre which terminates in a tip of specific shape; this may be an isotropic tip of spherical configuration.

Another method is to provide a distal portion having curved surfaces, such as cylindrical surfaces. The light-spreading portion may be larger than the diameter of the optical fibre or substantially the same size. The light spreading portion may be formed by removing the internally reflecting outer layer of the optical fibre over a portion of the probe or by providing an extended portion of the desired shape having no internal reflecting portion. Alternatively, the internal light reflecting coating may be omitted in the desired area when forming the coating. One method of forming such a tip is described in US Patent No. 5,073,402.

Essentially, the light-spreading distal tip may be conveniently formed by moulding or casting a curable light transmissive composition on the end of the optical fibre. A spherical tip may be formed by dipping the optical fibre into a polymerisable composition and curing the adherent droplet, while supporting the droplet in a non-miscible liquid. Curing may be effected by passing light of the appropriate wavelengths for curing along the optical fibre. Suitable polymerisable compositions include light curable acrylate and methacrylate compositions, including those described below as suitable sealant materials. It may be desirable to include a light-scattering material within the polymerisable material to increase the uniformity of irradiation of the root canal. However, the cured tip will be transparent or translucent to light of the wavelength selected for sensitising the dye.

Other shaped tips may be formed by moulding or casting the desired shape to the end of the optical fibre.

The Photosensitiser

The photosensitiser or dye is used for the disinfection of the internal surface of the root canal by placing a liquid or gel containing the photosensitiser in contact with the debris and bacteria. The interior of the root canal is then irradiated with light of an appropriate wavelength that will be absorbed by the photosensitiser.

In preferred aspects of the invention, the photosensitiser and laser combination may be applied to:-

(a) disinfection or sterilisation of the root canal after initial access has been gained to the root canal of the infected tooth; or as an adjunct to conventional preparation prior to obturate of the canal;

(b) destruction of carious microbes on the internal root surface in order to prevent reinfection.

Photosensitising agents used in this invention are generally non toxic to the target microbes in the concentrations envisaged or to the surrounding tissue. However, there is no requirement that the photosensitiser should not be toxic to the microbes. Since the exposure times are short, it may be acceptable to use compounds which have some slight toxicity to the tissue.

It is preferred that the photosensitisers used will be capable of absorption in the red end of the visible spectrum or at longer wavelength, as these wavelengths will have greater penetrating powers in the dental tissue surrounding the canal.

The preferred photoinitiators are those effective against Gram Negative bacteria associated with endodontic lesions, such as species of bacteroides, actimomyces, streptococci, lactobacilli and other anaerobic species. These are the dyes. Of these, the currently preferred is Toluidine blue O. Alternatively, aluminium disulphonated phthalocyanine chloride, methylene blue or azure blue chloride may be used. While the dye may be non specific, it can be made specific to the microbes within the root canal.

The Laser

The concentration of photoinitiator and laser power are matched to provide maximum penetration of tissue and kill rates.

The concentrations of dye range from 0.00001% to 2%. The currently preferred concentration is 0.0001 to 0.2%, especially 0.001 to 0.1%.

The preferred laser irradiation time of the photosensitiser is between 10 seconds and two minutes and the preferred exposure time is between 30 seconds and 90 seconds.

The laser power is preferably between 25 and 80 mW, the most preferred being about 60 mW. The laser power/exposure time combination may be varied to give a desired dose.

The photosensitiser solution concentration may be influenced by any extrinsic fluid and concentration may be increased to compensate for this.

In order to modify the surface of hard tissue and to enable the photosensitising agents to have maximum effect, potentiating agents may be used as adjuncts to the photosensitising solution. These may include:-

- Acids to produce a solution pH of 4.5 or above
- Acids to penetrate and remove organic/inorganic debris
- Wetting agents such as HEMA (hydroxyethyl methacrylate) and glutaraldehyde
- Demineralising agents such as chelating agents of the type EDTA disodium.

Such materials may be citric acid, polyalkenoic and polyphosphonic acid, phosphoric acid, EDTA and HEMA or other such acids as are known for use in this technique. These may be used prior to and/or subsequent to application of the photosensitiser.

It is important that these agents do not interfere with the photosensitising process, in particular the use of free radical and singlet oxygen scavenging materials should be avoided.

The photosensitiser may be delivered by a syringe but more preferably by a thin flexible tube which is perforated along the final part of its distal end, e.g. the last 15 mm of its length. The perforated tube, whose diameter is preferably a maximum of 0.1 mm, will be inserted up the canal without binding against the walls. This will normally be within the apical third of the canal (this being the third of the root canal closest to the root apex), and as close to the apex as achievable without binding on the walls. The dye is then injected, e.g. via a unit dose cartridge, through the tube permitting the dye to coat the whole length of the walls of the root canal. The unit dose syringe and tube will then be removed and the fibre connected to a suitable light

source and inserted into the canal. The photosensitiser dye will be activated by the light source.

The filling or sealing material

A further aspect of the invention is that a fluid sealing agent may be syringed up through the delivery system previously described in connection with the photosensitiser. This will coat the walls of the root canal and displace air from the canal as it fills the canal through a tube or syringe tip terminating in the region of the apex. The sealing agent may then be cured using a visible light source, via an optical fibre tipped with an isotropic tip.

These may be resins such as those described as dental adhesives in Patent Application Nos. PCT/GB92/02128; PCT/GB98/00072; US 5,172,763 and US 5,063,257, and other curable resin systems which are employed as dental adhesive and filling materials. Preferably, the sealing or filling material is light-curable. The preferred resin system is one containing combinations of tetrahydrofurfuryl methacrylate (THFMA), urethane dimethacrylate (UDMA) and BisGMA) which contain THFMA in the range of 30-90% by weight of THFMA. These resin systems will also contain initiators such as α diketones and amines using a light source operating at 460-470nm.

Alternative materials such as sol-gel glasses may also be used as the sealing agents delivered in a similar manner to that described above.

The accompanying drawings illustrate the manner in which the invention may be carried into effect.

Figure 1 is a schematic longitudinal cross-section through a tooth with one m of optical fibre in place in a root canal;

Figure 2 is a section of an enlarged scale of the optical fibre;

Figure 3 is a section through a single dose device for delivering a photosensitiser solution into the root canal.

The tooth (1) is first drilled to access the entrance (2) to the infected root canal (3), and loose debris suctioned away. A photosensitiser solution, e.g. Toluidine blue O, in dilute aqueous solution (concentration about 0.001%), is then introduced into the root canal using a fine-tipped syringe or a disposable dispenser such as shown in Figure 3. Referring to Figure 3, the dispenser comprises a thin-walled cannula (10) having a reservoir (11) for photosensitiser solution attached to its proximal end. The connection between the reservoir and the cannula is sealed with a frangible membrane 12. At its distal end, the cannula is perforated with small holes (13) which permit the escape of liquid from the cannula. In use, the cannula is inserted into the root canal until the distal end is close to the apex of the canal. Photosensitiser is discharged into the root canal by pressing on the reservoir (11), thus causing the membrane to rupture and liquid to flow out of the distal end and through the perforations (13). The perforations (13) ensure that the walls of the root canal are wetted with photosensitiser solution. Preferably, the photosensitiser is allowed to remain in contact with the root canal to permit the photosensitiser to be absorbed by bacteria within the canal, normally about 20 to 40 seconds. The dispenser is then removed and an optical fibre (20), as shown in Figure 2, is introduced into the root canal (3) and laser light having a wavelength of about 630/640 nm guided into the canal.

As can be seen best in Figure 2, the optical fibre is formed with a transparent distal spherical portion (21), typically of about 800 microns diameter. This has the effect of diffusing light passed down the fibre and ensures that light emerging at the tip (21) is scattered uniformly around and in upward and downward directions in the root canal.

It may be desirable to move the tip of the optical fibre relatively to the canal, either stepwise or continuously, while irradiating the interior of the canal. For example, the tip may be inserted initially to the apex of the canal and then gradually withdrawn, while irradiating the canal. This may be facilitated by the fibre carrying incremental markings on its external surface similar to the tip dimensions. The operator may withdraw the tip incrementally, using the marks to ensure that irradiation of the photosensitiser is carried out over the whole canal length. Instead of an optical fibre having a spherical tip, a fibre having a generally cylindrical distal part may be used. For example, the tip may comprise a 3mm long cylindrical tip having a diameter of about 200 microns. This has approximately the same area as the spherical tip referred to above.

After the photosensitiser has been irradiated with laser light for a sufficient period to ensure sterilisation of the interior of the canal (usually 30 seconds to 1 minute at a laser power of between 40 - 80 mW), the optical fibre is removed.

It may be desirable at this point to aspirate photosensitiser from the canal.

A fluid sealing or filling composition is then introduced into the canal. For this purpose, a unit dose dispenser such as that shown in Figure 3 may be used. An optical fibre such as shown in Figure 2 may then be introduced into the root canal and

light passed down the fibre to cure the sealant material. This will hermetically seal the root canal from reinfection. The sealant material may incorporate a radio-opaque filler material, such as a barium or strontium salt, e.g. the fluoride. It may further contain amine fluoride. The projecting part (24) of the optical fibre may then be cut off and the access hole (25) may be filled with a conventional dental filling material such as an amalgam or glass ionomer resin.

A more developed version of the laser console and a dental handpiece carrying the optical fibre is shown in Figures 4 and 5. Figure 4 shows a perspective view of the laser housing (41) linked to a dental handpiece (42). An optical fibre (43) is held in the part of the handpiece which will be introduced into the patient's mouth. The optical fibre (43) is a disposable "plug in" element which carries an isotropic tip as described above in relation to Figures 1 to 3. Housing (41) contains laser generating equipment whose output is connected to a flexible heavy duty optical fibre within the handpiece, the output from the fibre (44) is connected to the disposable fibre (43).

Figure 5 shows a control panel (45) having a touch screen (46) for programming the laser power and duration of treatment. For convenience, the apparatus can be made in portable form and incorporate a rechargeable battery.

Alternatively, the sterilised canal may be sealed by means of gutta percha plugs supported on a plastic or metal rod-like carrier as described in EPA 0337024 or USA 5149268.

CLAIMS:-

1. A method of treating a dental root canal which comprises the steps of:-

(a) gaining access to the root canal;

(b) introducing a flowable photosensitiser into the root canal;

(c) activating the photosensitiser by exposing the walls of the root canal to light via an optical fibre within the root canal to kill bacteria within the root canal and pulp chamber; and

(d) obturating the root canal.

2. A method according to claim 1 wherein the root canal is obturated with gutta percha, silver or titanium points.

3. A method according to claim 2 in which the root canal is obturated with an obturation device comprising gutta percha carried on a rod-like carrier, the device being shaped and dimensioned so that on forcing it into the canal, the gutta percha is deformed and fills the canal.

4. A method according to claim 1 in which the root canal is obturated with a curable filling material.

5. A method according to claim 4 wherein the curable filling material is cured by irradiation with light through an optical fibre within the root canal.

6. A method according to claim 5 wherein the same optical fibre is used for activating the photosensitiser and the curable filler material.

7. A method according to any one of the preceding claims wherein the optical fibre has a substantially isotropic tip.

8. A method according to any one of the preceding claims in which the optical fibre has a spherical or cylindrical portion at or close to the distal end to spread radiation around and along the canal.

9. A kit of parts for treating a dental root canal which comprises:-

(a) a flowable photosensitiser;

(b) an optical fibre having a portion at or close to the distal end which is shaped to spread radiation around and along the canal, said fibre being adapted for introduction into a root canal so that the tip is capable of reaching the apical third of the root canal, said optical fibre being connectable proximally with means for generating laser light; and

(c) obturating means for sealing the canal.

10. A kit according to claim 9 wherein the flowable sensitiser comprises a dilute aqueous solution of toluidine blue.

11. A kit according to claim 9 wherein the obturating means comprises a preformed plug of gutta percha or silver or titanium points.

12. A kit according to any one of the preceding claims wherein the flowable sensitiser is contained in a cartridge which includes a delivery tube for introducing the photosensitiser into the canal.

13. A kit according to claim 9 wherein the obturating means comprises a flowable, curable sealing composition.

14. Use in the manufacture of materials for sterilising and sealing a dental root canal of a kit of parts comprising:

(a) a flowable photosensitiser;

(b) an optical fibre which is shaped and dimensioned to pass into a root canal to the region of the apex thereof, said optical fibre being connectable proximally with means for generating laser light at a wavelength which is capable of being absorbed by the photosensitiser and said optical fibre having a distal portion which is shaped to spread the laser light around and along the canal; and

(c) obturating means for sealing the canal.

15. Use according to claim 14 in which the photosensitiser is an aqueous dye.

16. Use according to claim 15 in which the photosensitiser is toluidine blue in aqueous solution.

17. Use according to any one of claims 14 to 16 in which the obturating means comprises gutta percha supported on a rod-like support.

18. Use according to any one of claims 14 to 16 in which the obturating means comprises a light curable resin composition.

Fig 1

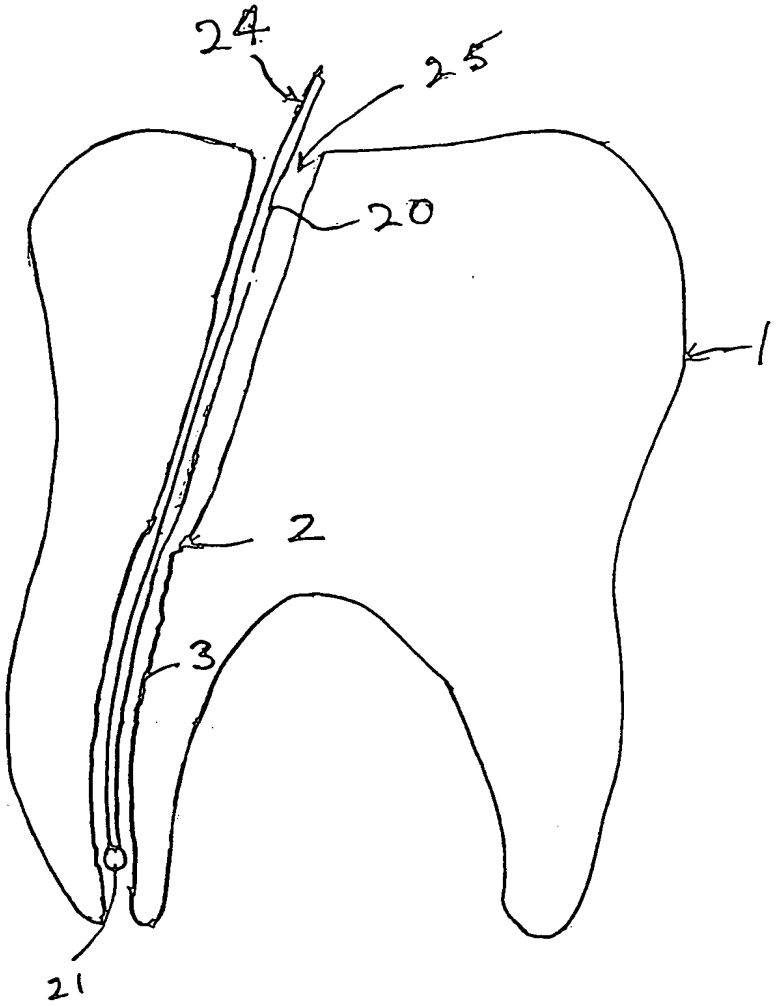


Fig 2

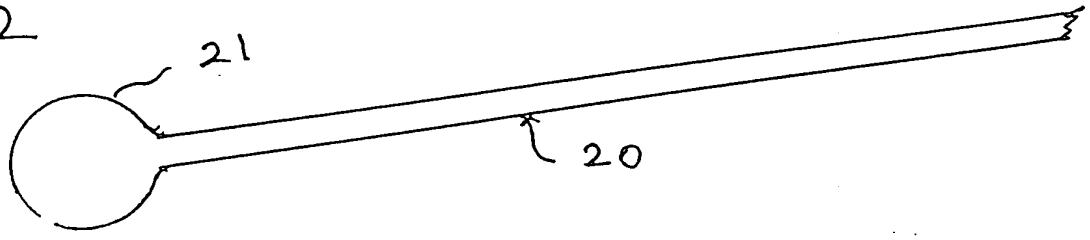


Fig 3

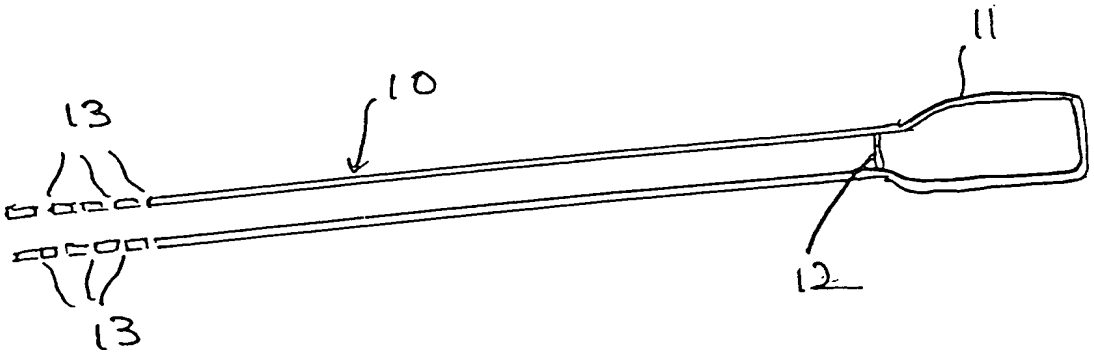


Fig 5

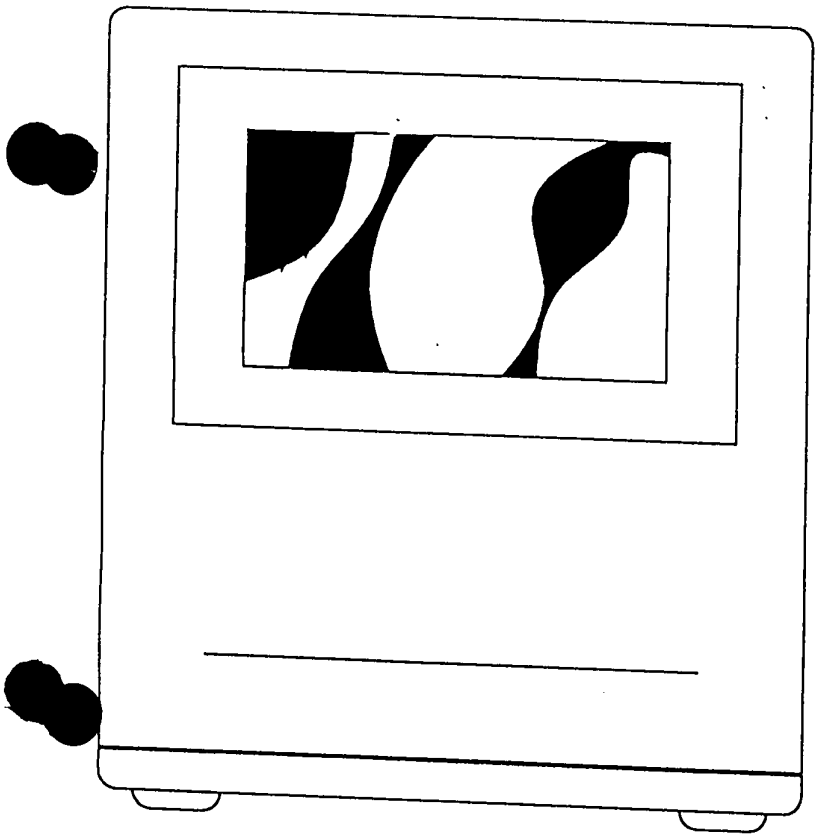
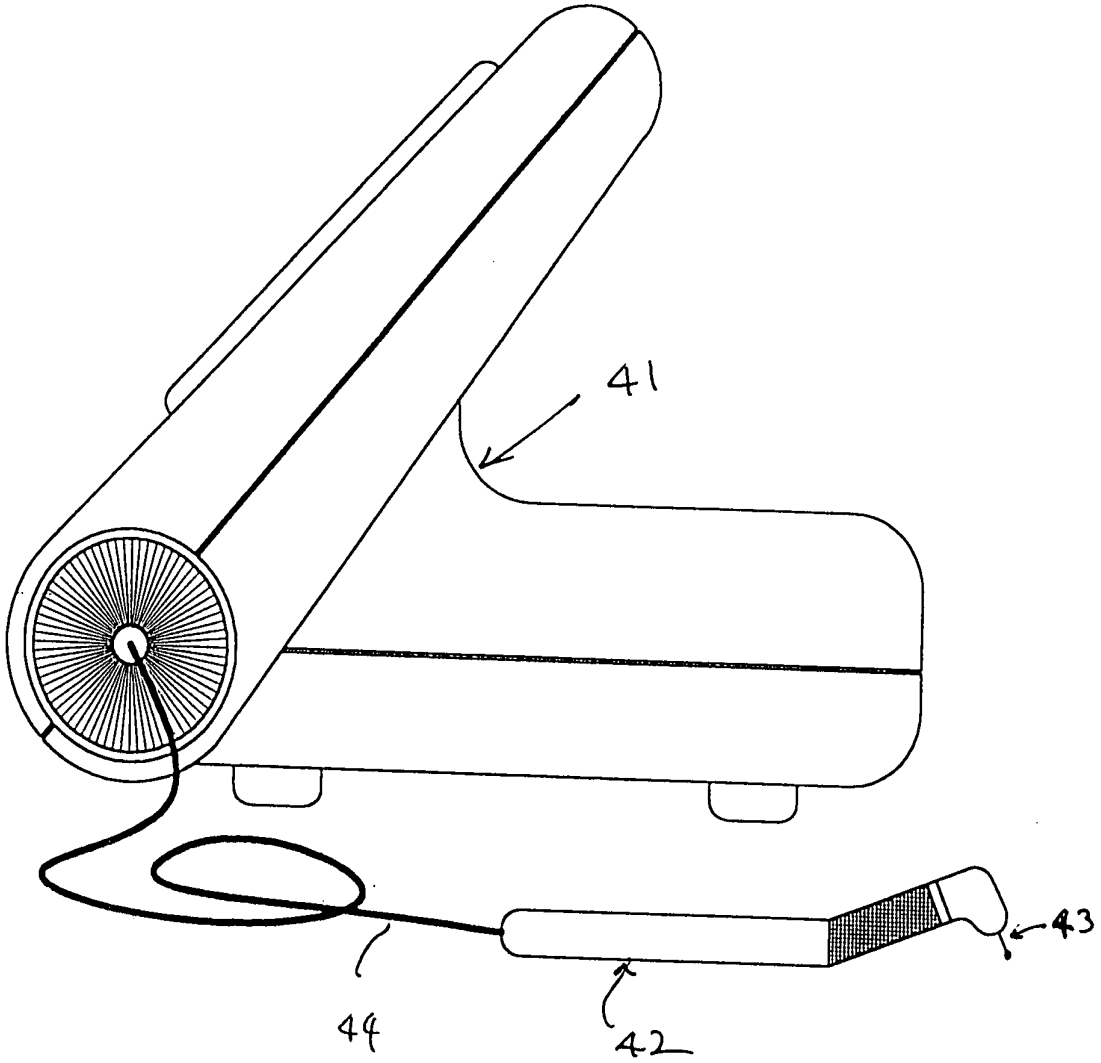


Fig 4



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